

Remarks

The abstract has been amended to less than 150 words.

The specification has been amended on page 14 to describe that tubing 18 may be of a larger diameter than working channel 28d. This is not new matter as this is shown by comparison of the diameters of the tubing 18 and working channel 28d of FIG. 1B of the application. Accordingly, entry of the amended specification is requested.

Claims 1-44 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent Nos. 5,792,153 (Swain '153) and 5,755,730 (Swain '730) in view of U.S. Patent No. 5,954,731 (Yoon). Because the Examiner refers to Applicants' written description rather than the claims, when he explains the relevance of the references, it is a little difficult to see exactly how the Examiner is applying the references to the claims. Nevertheless, Applicants have amended Claim 1 to even more particularly point out and distinctly claim the invention. Before considering the amended claim or the references in detail and before specifically addressing the rejection, it may be helpful to briefly review Applicants' invention. As now claimed, the invention relates to a system for endoscopic suturing that provides a number of advantages over systems heretofore known. Claim 1 is not directed to an endoscope, but to a system that enhances an endoscope of the type having a flexible shaft, with a flexible tube attached to a distal end of the shaft of the endoscope to operate as a conduit for guiding one or more instruments. The system further comprises in Claim 4 a tissue suturing instrument having a shaft which is sufficiently flexible to be locatable through the flexible tube.

The two Swain references are examples of endoscopes over which the present invention is an improvement. Swain '153 describes a device for use in endoscopic procedures. FIGS. 1 and 2 show most clearly how the device operates. The unitary instrument consists of a sewing device indicated generally at 2 attached to a flexible endoscope 1. While the mode of attachment isn't described in much detail, it is clear that the sewing device is permanently attached to the endoscope 1 to form a single instrument. The endoscope portion of the device is not described in much detail except to note that it has a biopsy channel 3 and a suction channel 4 which appear to be utilized to operate the sewing device. The suction channel draws tissue 19 into position for suturing and the needle is apparently operated by a wire that extends down the biopsy channel.

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The most significant disadvantage of the device shown in Swain is that because the endoscope and the sewing device are combined into a single unit, it is necessary, as Swain

describes in column 2, lines 54 *et seq.* to withdraw the endoscope and the sewing device from the patient to tie the ends of the thread. As Swain '153 puts it

Finally, the endoscope and the sewing device are withdrawn from the patient. In so doing, the thread 14 is pulled partially through the tissue portion 19a since the tag 12 is trapped in the chamber 20. The end result is that both ends of the thread are outside of the patient and can be knotted and/or severed as may be appropriate.

This is a significant disadvantage, especially when more than one stitch needs to be taken during a procedure. Moreover, repeated insertion and withdrawal of an endoscope during the procedure is at best not helpful to a patient and at worst may irritate the passage along which the endoscope is repeatedly inserted and withdrawn. Applicants' invention represents an improvement over the device shown in Swain '153.

Swain '730 is related to a device for use in cutting threads. The device comprises a cutting head mounted on the distal end of a flexible wire (column 1, lines 39-40). The thread cutter is intended to be inserted into an endoscope to capture and then cut two thread tails 13 which pass outside the body of the endoscope 1. The Examiner has not described and Applicants do not see how the two devices of Swain '153 and '730 are related to each other. At best, the device shown in Swain '730 might be used to cut sutures placed by the device shown in Swain '153, but if this were done, two distinct endoscopes would be used one after another in completing the procedure. Even though the inventions were filed at about the same time, there is no suggestion either that they could be used together and, most important, there is no suggestion that a sewing device like the one shown in Swain '153 would be used together with an endoscope of the type shown in Swain '730. In fact, there would be no need to do so because the Swain '153 sewing device has its own endoscope 1 to which it is attached. No advantage would be obtained by combining the Swain '153 device with another endoscope. The Examiner acknowledges as much when he says that the two Swain references do not teach a system in which the suturing and cutting functions are performed within one endoscopic device.

Applicants agree with this and suggest that the Swain references, in fact, teach away from combining the suturing and cutting functions. The Swain '153 reference, because it includes an endoscope permanently attached to the suturing device, neither shows nor suggests any method or structure for adding a cutting function. Likewise, Swain '730 is completely silent as to the manner in which the suture in which it is designed to cut is placed. Assuming that the Swain '153 device is used to place the suture, the combined teachings of Swain '153 and Swain '170

are to use separate instruments to place and cut a suture, not to combine them with one endoscopic device. Both of the Swain patents are examples of unitary devices that include an endoscope and another instrument.

To this combination the Examiner adds Yoon. Yoon relates to a rigid endoscope having a variety of end effectors. While Yoon describes only forceps, he mentions that other types of end effectors can be used, including but not limited to, cauterizing electrodes, needle holders, dissectors, clip applicators, staplers, scissors, cutting members such as blades, needles and biopsy devices. Significantly, suturing and suture cutting end effectors are not mentioned.

Yoon has a shaft having a channel for receiving an endoscope or other instrument as described at column 13, lines 15-21, is not itself an endoscope. Moreover, Applicants find no suggestion in Yoon that the device has a steerable distal end, as called for in Claims 31 and 32, and new Claims 56-58 and 68-69. It is clear that the major advance provided by Yoon is related to the end effector assemblies. As Yoon puts it, an object of the invention is to permit multiple end effectors to be used in combination in a surgical procedure without the need of having to use multiple instruments. Another object is to increase the working span or range of movement of multiple end effectors carried by a single instrument while minimizing the insertion diameter of the instrument. Because Yoon is entirely focused on providing a single instrument, there is no mention or suggestion to provide a flexible guide tube outside of the shaft of the instrument and Applicants respectfully submit that it would be contrary to the expressed purposes of Yoon to do so. Moreover, nothing in Yoon describes or suggests a tissue suturing instrument of Claim 4 having a shaft which is sufficiently flexible to be locatable through the first and second ends of a tube. Not only is there no basis, either in the references themselves or in any other prior art referred to by the Examiner, to somehow combine the teachings of Swain and Yoon, and even if such combination was made, the present invention would not be the result. The present invention permits an endoscope to be inserted once during a procedure with the suturing instrument inserted and removed through the guide tube as necessary to complete the procedure. The following will now discuss the Claims of the present Application in more detail.

Claim 1, as amended, describes a system having a flexible tube attachable at one or more locations along the outside of an endoscope's shaft to enable the tube to flex with flexing of the endoscope's shaft. Neither Swain '153, Swain '730, nor Yoon, describe or suggest such a flexible tube. Swain '153 shows a sewing device at the distal end of an endoscope (see Swain '153 at column 1, lines 50-55), and Swain '730 shows a suture cutting device at the distal end of another endoscope (see Swain '730 at column 1, lines 31-37). Such devices of Swain '153 and

'730 do not provide any flexible tube coupled to their respective endoscope. Yoon's instrument has an elongated shaft, but such shaft is not described or suggested by Yoon as being attachable along the outside of an endoscope's shaft. It appears to be the Examiner's position that passage of the devices of Swain '153 or '730 through the internal channels of Yoon's shaft provides Claim 1. However, it is submitted that the combination of Swain '153 or '730 with Yoon clearly fails to show Claim 1 where there is no teaching or motivation to attach a flexible tube attached along the outside of an endoscope's shaft, whereby it can flex with the such shaft and serve as a conduit for one or more instruments. See In re Vaeck, 20 USPQ2d 1438, 1442 (Fed Cir. 1991). The Examiner's combination actually teaches away from attachment to an endoscope outside of Yoon's shaft, since there would already be an endoscope present by the endoscope of each device of Swain '153 or '730 (see Swain '153 at column 1, lines 50-55, and Swain '730 at column 1, lines 31-33).

Moreover, the combination of Swain '153 or '730 with Yoon fails to describe or suggest the tip of Claim 1. No tip is shown or described in these patents attachable to the distal end of an endoscope having an opening for an end of a flexible tube. Yoon is clearly limited to passage of instruments through internal channels, such as forceps, but this clearly would not motivate one skilled in the art to provide a distal tip attaching any flexible tube to an endoscope, especially where Yoon does not show a flexible tube located outside any endoscope's shaft to flex with flexing of such shaft. Claim 1 has been amended to clarify the invention, rather than to overcome the rejection. Accordingly, Claim 1 is patentable over Swain '153 and '730 and Yoon, either alone, or in combination, and Applicants request that the rejection of Claim 1 be withdrawn. Applicants also request withdrawal of the rejection of dependent Claim 19, which adds to the system an endoscope representing a gastroscope.

Claim 2, as amended, describes a plurality of tube guides, each of the tube guides being attachable at a different location along the outside of the endoscope's shaft and has an opening through which said flexible tube extends, and the flexible tube is slidable through the opening in response to flexing of endoscope's shaft. For the reasons argued above, no flexible tube is described in Swain '153 or '730, or Yoon, and no elements are provided in Swain '153 and '730 and Yoon comparable to such tube guides. Moreover, even if Swain '153 or '730 passed through the channels of Yoon's shaft, as the Examiner contends, why would guides be needed if the Swain '153 or '730 devices are already being guided through Yoon's channels. Thus, Claim 2 is patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claim 3, as amended, describes a cannula attached to the first end of the flexible tube of Claim 1 in which one or more instruments of Claim 1 can pass through the cannula into the flexible tube. Clearly, no cannula is attached to any flexible tube in Swain '153, Swain '730, or Yoon through which instruments may pass through into a flexible tube. Therefore, Claim 3 is patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claim 4 describes at least one of the instruments as a suturing instrument having a shaft sufficiently flexible to enable passage through the flexible tube. As a result of the absence of the flexible tube of Claim 1 in Swain '153 and '730 and Yoon, there can be no suturing instrument which can pass through such flexible tube. Claims 5, 6, 7, and 26 further describe the suturing instrument of Claim 4. Thus, Claims 4-7 and 26 are patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claims 8-18 further describe the suturing instrument of Claim 4. It is the Examiner's position that Swain '153 shows these Claims. However, Swain '153 other than describing that its distal end of FIG. 1-9 is mounted on the end of an endoscope, does not describe the elements of Claims 8-18. Claim 8 describes the shaft of the suturing instrument as having first and second sections in which the first section is rigid and the second section is flexible. Swain '153 clearly lacks a description or suggestion of its shaft having any such shaft sections by its description of its distal end. Claims 9 and 10 describe first and second guide members, tracks of such guide members, and a coupler member for coupling such guide members. No such guide members or coupler member are described in Swain '153. Claim 11 describes means for translating rotation of one of the housing and the first section to the second section and the tissue engaging end of the suturing instrument. No such translation of rotation is described in Swain '153. Claim 12 describes the needles that extend through the shaft. Since the first and second sections of the shaft of the suturing instrument of Claim 8 are absent in Swain '153, then the needles passing through such shaft cannot be present. Claim 13 describes one or more needles in the shaft of Claim 8 having first and second members and a spring coupling the first and second members. As shown in the figures of Swain '153, the needle 8 or 60 has an attached wire wound cable 10 or 40, and a central wire 11 or 41 through the biopsy channel 3 of its endoscope. Hence, needle 8 or 60 clearly lacks the two members and spring of Claim 13. Claims 14-18 depend on Claim 13. Claim 14 further describes the shaft of the suturing instrument as having a tube with holes for such needles extending through the second section of the shaft, while Claim 15 describes a tube for each of the needles through the second section of the shaft. No tube of either Claims 14 or 15 is described in any shaft in Swain '153. Claim 16 further describes the spring of Claim 13

with an outer sheath to restrict elongation of the spring while enabling flexure of the flexible tube of the second section of Claim 15, while Claim 17 describes the spring of each of the needles of Claim 13 as assisting in flexibility of the needles. The wire wound cable 10 or 40 of the needle 11 or 41 of Swain '153 is not comparable to the claimed spring since it is provided to assist in driving the needle, and not for the purpose of assisting in needle flexibility, see column 2, lines 38-51, of Swain '153. Claim 18 describes a cable or wire coupling the spring of Claim 13 between the first and second members, and such cable or wire is not present in Swain '153 between any first and second members. Thus, Claims 8-18 are clearly patentable over Swain '153 and '730 and Yoon, either alone, or in combination, and withdrawal of the rejection of these claims is requested.

Claim 20 describes the instruments of Claim 1 that can pass through the accessory tube as operating independent of an endoscope. Swain '153 and '730 cannot operate independently of any endoscope since they are mounted upon an endoscope and even utilize the biopsy channel of an endoscope (see endoscope's biopsy channel 3 of Swain '153 at column 1, lines 57-58, and column 2, line 1, or biopsy channel 2 of Swain '730 at column 1, lines 32-33 and 51-54). Thus, Claim 20 is believed patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claim 21 describes at least one of the instruments of Claim 1 as representing a suture securing instrument, and Claim 22 further describes the shaft of the suture securing instrument as being at least partially flexible to enable passage through the flexible tube. As a result of the absence of the flexible tube of Claim 1 in Swain '153 and '730 and Yoon, as argued earlier, there can be no suturing instrument which can pass through such flexible tube. Thus, Claims 21 and 22 are patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claim 23 describes the suture securing instrument of Claim 21 having means for retaining in a sleeve member the two free ends of a loop of suture extending through tissue, and means for cutting the two free ends of the loop of suture near the sleeve member. It is the Examiner's position that the device of Swain '730 for cutting threads represents the suture securing instrument. However, Swain '730 at best describes a securing knot 12 (see Figures 1-4), and lacks means for retaining the two free ends of suture in a sleeve member. Claim 23 is therefore believed patentable over Swain '153, Swain '730 and Yoon, either alone, or in combination.

Claim 24 describes the suture securing instrument of Claim 21 as not being part of an endoscope. Swain '153 and '730 cannot operate independently of any endoscope since they are

mounted upon an endoscope, and even utilize an endoscope's biopsy channel 3 of Swain '153 (column 1, lines 57-58, column 2, line 1) or biopsy channel 2 of Swain '730 (column 1, lines 32-33 and 51-54) to operate their devices. Claims 24 is thus patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claim 25 describes the shaft of at least one of the instruments of Claim 1 as having a distal end, and the endoscope as having means for viewing the distal end of one of the instruments located through the flexible tube of Claim 1. Although Swain '153 and '730 are integral with an endoscope, neither of their devices is located through any flexible tube attached to an endoscope as called for in Claim 1, even if combined with Yoon. Thus, Claim 25 is patentable over Swain '153, Swain '730, and Yoon, either alone or in combination.

Claim 27 describes a port on the flexible tube of Claim 1 for enabling suction to be provided to the distal tissue engaging end of the suturing instrument of Claim 4 via an opening in a channel of the tissue engaging end. No such port on a flexible tube and opening in a channel of a tissue engaging end for providing suction is present or even suggested in Swain '153, even in combination with Swain '730 and Yoon. Thus, Claim 27 is patentable over Swain '153 or '730, and Yoon, either alone or in combination.

Claim 28 describes the endoscope in the system of Claim 1 having a shaft attached to the flexible tube and the tip. There is no flexible tube or tip attached to any endoscope in either Swain '153 or '730, or Yoon, as argued earlier. Thus, Claim 28 is patentable over Swain '153, Swain '730, and Yoon, either alone or in combination.

Claim 29 describes means for locking the position of the at least one of the instruments of Claim 1 with respect to the flexible tube at the tip of the flexible tube. Again, there is no flexible tube or tip coupled to any endoscope in either Swain '153 or '730, or Yoon, as argued earlier. Moreover, there is no means for locking even suggested by the combination of such patents.

With respect to Claim 30, there clearly are no protrusion members along the outer surface of the distal end of either devices of Swain '153 or '730, and no tip having an opening with one or more slots into which such protrusion members are receivable to lock the position of any instrument. Thus, Claim 30 is patentable over Swain '153, Swain '730, and Yoon, either alone or in combination.

Claims 31 and 32 describe means for steering the distal tissue engaging end of the suturing instrument of Claim 4. No such steering means is shown at the distal of the sewing device of Swain '153, even in combination with Swain '730 and Yoon. Claim 32 further describes the steering means as being one of hydraulically and mechanically actuated. Thus,

Claims 31 and 32 are patentable over Swain '153, Swain '730, and Yoon, either alone or in combination.

Claim 33 describes a method for suturing tissue by providing an endoscope having a flexible shaft and an accessory tube coupled externally to the shaft which flexes in accordance with flexing of the shaft, locating an endoscope with the coupled accessory tube in the body of a patient, and inserting a suturing instrument through the accessory tube into the body of the patient to place two ends of a loop of suture through tissue. For reasons argued earlier, no flexible shaft of an endoscope is coupled to any accessory tube in Swain '153 or '730, or Yoon, that flexes in accordance with flexing of an endoscope's shaft, or can be located in the body of a patient for passage of any instrument through such accessory tube. Therefore, Claim 33 along with dependent Claim 34 are patentable over Swain '153, Swain '730, or Yoon, either alone, or in combination, and withdrawal of the rejection of Claims 33 and 34 is requested.

Claim 35 describes an attachment for a flexible endoscope having a flexible tube capable of being coupled externally to the shaft of an endoscope to be flexible with flexing of such shaft, where the flexible tube has a distal end attached to such shaft. No suggestion of any flexible tube having a distal end attached to the shaft of an endoscope is provided in Swain '153, Swain '730, or Yoon, either alone, or in combination. Claims 36-39 depend on Claim 35. Claim 36 describes the attachment of Claim 35 as have a sealable opening at the proximal end of the flexible tube. Claim 38 describes the sealable opening as being provided by a cannula. No flexible tube having any sealable opening is shown in Swain '153 or '730, or Yoon. Claim 37 describes a plurality of guides attached to the shaft of an endoscope through which the flexible tube is slidable. Clearly, it cannot be obvious to add guides to Swain '153 or '730, or Yoon, since there is no flexible tube to be used with such guides. Moreover, even if Swain '153 or '730 passed through the channels of Yoon's shaft, as the Examiner contends, why would guides be needed if the Swain '153 or '730 devices are already being guided through Yoon's channels. Claim 39 describes the flexible tube of Claim 35 as representing a conduit enabling access of an instrument independent of the endoscope near the distal end of the shaft of the endoscope. No flexible tube attached external to an endoscope is provided for in Swain '153 or '730, or Yoon, which represents a conduit enabling access of an instrument independent of the endoscope near the distal end of the shaft of the endoscope. Accordingly, withdrawal of the rejection of Claims 35-39 is requested.

Claim 40 describe a suturing instrument having a shaft with a first rigid section and a second flexible section. There is no description or suggestion of any shaft having a first rigid



section and a second flexible section in the sewing device of Swain '153, even in combination with Swain '730 or Yoon. Claim 41 depends on Claim 40 and further describes a capped sleeve over a sew tip of the suturing instrument, means for selectable providing suction to a suturing channel along the instrument's shaft in which the capped sleeve enables suction to be communicated to the distal end of the instrument, and means for selectable closing an end of the suturing channel to enable such suction to be provided to the sew tip. No capped sleeve and means for selectable closing a suturing channel to enable suction is described or suggested by the sewing device of Swain '153. Claim 42 describes the needle as having first and second members and a spring which couples the first and second members, and the second member has a tip positionable in the sew tip of Claim 40. As shown in the figures of Swain '153, the needle 8 or 60 has an attached wire wound cable 10 or 40, and a central wire 11 or 41 through the biopsy channel 3 of the endoscope. Hence, needle 8 or 60 lacks two members and any spring between such members. Withdrawal of the rejection of Claims 40-42 is thus requested.

Claim 43 describes a suture securing instrument having a shaft which is at least partially flexible, a distal end coupled to the shaft, means at the distal end for retaining in a sleeve member the two free ends of a loop of suture, and means for cutting the two free ends of the loop. The cutting device of Swain '730 has no means at its distal end for retaining in a sleeve member the two free ends of a loop of suture, even in combination with Swain '153 or Yoon. A device for cutting threads of Swain '730 is not comparable to any means for retaining the ends of a loop of suture in a sleeve member. Accordingly, withdrawal of the rejection of Claim 43 is requested.

Claim 44, as amended, describes a system for endoscopic suturing in the body of a patient having an endoscope with a shaft and an internal channel along the shaft locatable in the body of a patient, a suturing instrument having at least a partially flexible shaft which is locatable through the internal channel of the endoscope to locate at least one loop of suture in the body of a patient, and a suture securing instrument having at least a partially flexible shaft which is locatable through the internal channel of the endoscope to retain in a sleeve member the loop of suture and then cut the suture extending from the sleeve member to secure the suture in the body of the patient. First, the sewing device of Swain '153 and cutting device of '730 are mounted upon an endoscope, utilizes an endoscope's biopsy channel 3 of Swain '153 (column 1, lines 57-58, column 2, line 1) or biopsy channel 2 of Swain '730 (column 1, lines 32-33 and 51-54) to operate their respective devices, and both have a viewing channel conventional to endoscopes (see column 1, lines 52-54, of Swain '153, and column 1, lines 35-36, of Swain

'730). Thus, there is no reason for passing the devices of Swain '153 or '730 through an internal channel of another endoscope, as their devices already incorporate features of a conventional endoscope, and the biopsy channel of such endoscope is presently in use. Yoon is not an endoscope, as it lack the important feature of an endoscope, i.e., viewing. Second, as stated earlier, the cutting device of Swain '730 fails to retain any suture through a sleeve member. Thus, the combination of Swain '153, Swain '730, and Yoon does not describe or suggest any endoscope having a channel through which the claimed suturing and suture securing instruments may pass through.

Claims 2-4, 7-22, 24-30, 33-41, 43, and 44 were amended to clarify the invention, rather than to overcome any rejection of such claims.

Claims 45-53 have been added into the application. Claim 45 describes the flexible tube of Claim 1 as being attachable to and detachable from different types of endoscopes. Neither Swain '153, Swain '730, nor Yoon, describes any flexible tube which is attachable to and detachable from different types of endoscopes. Claim 46 adds to the system of Claim 1 an endoscope having a shaft with a channel for passage of tools, and the flexible tube is of a diameter larger than such channel. There is no flexible tube in Swain '153, Swain '730, or Yoon having a diameter larger than the tool passing channel of an endoscope. Claim 47 describes each of the instruments of Claim 1 as being sufficiently flexible to be locatable through the first and second ends of the tube when having one or more flexures in accordance with flexing of a shaft of the endoscope. Again, without the claimed flexible tube, neither Swain '153, Swain '730, nor Yoon, no flexible tube is present in the combination of Swain '153, Swain '730, and Yoon, capable of having any flexures in accordance with flexing of the shaft of an endoscope. Claim 48 depends on Claim 22 and describes the suture securing instrument as being locatable through the internal channel of an endoscope. There is no suture securing instrument having at least a partially flexible shaft located through the internal channel of any endoscope in Swain '153, Swain '730, or Yoon. Claims 49 and 50 are dependent on Claim 33 and have language removed from Claim 33. Claim 51 depends on Claim 35 and describes one or more first members attachable to the shaft of an endoscope for the flexible tube to slide through, and a second member attached to the distal end of the tube and shaft of an endoscope, in which the tube operates as a conduit for passage of one or more instruments along outside the shaft of the endoscope. No first or second members are attached to any endoscope in Swain '153, Swain '730, or Yoon. Claims 52 and 53 are dependent on base Claim 43 and have language removed

from Claim 43. Applicants believe that Claims 45-53 are patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claims 54-63 are also added to the application. Claim 54 describes a suturing instrument having a shaft which is not part of an endoscope, as oppose to sewing device of Swain '153 which is integrated with an endoscope. Claim 55 describes a capped sleeve for use in applying suction in Claim 54. Claim 56 describe a foldable piston coupled to the tissue engaging end of Claim 54 and means for controlling the volume of a medium in the foldable piston to steer the tissue engaging end. Claim 57 describes a cylinder having a movable piston coupled to the tissue engaging end of Claim 54 and means for controlling the volume of a liquid in the cylinder to steer the tissue engaging end. Claim 58 describes a wire extending along the shaft of the instrument of Claim 54, which is coupled to the tissue engaging end, and means for controlling the length of the wire along the shaft to steer the tissue engaging end. Claim 59 describes the suturing instrument of Claim 54 as being locatable through an internal channel of an endoscope, while Claim 60 describes the suturing instrument as being locatable through an accessory tube located outside along a shaft of an endoscope. Claim 61 further describes the shaft of the instrument of Claim 54 as having means for translating rotation from a first shaft section to both the second shaft section and the tissue engaging end of the instrument. Claim 62 further describes each of the needles as having a spring which couples first and second members of the needle to aid in flexibility of the needles. Claim 63 adds to each needle of Claim 62 a cable or wire which couples the spring between the first and second members. Applicants believe that Claims 54-63 are patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claims 64-65 have also been added to the application. Claim 64 describes a suturing instrument having one or more needles in which each of the needles has first and second members and a spring coupling the first and second members to add in flexibility of the needles. No needle is described or suggested in Swain '153, Swain '730, or Yoon having either the claimed first and second member, or a spring coupling such members. Claim 65 adds to each needle of Claim 64 a cable or wire which couples the spring between the first and second members. Accordingly, Claims 64-65 are also believed patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claims 66-67 have further been added to the application. Claim 66 describes an instrument for suturing tissue capable of translating of rotation between a first section of the shaft of the instrument to tissue engaging end of the instrument through a second section of the

shaft. No such translating of rotation is provided for in Swain '153, Swain '730, or Yoon. Thus, Applicants believe that Claim 66 and dependent Claim 67 are patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claim 68 has been added to the application. Claim 68 describes a cylinder having a piston coupled to the distal end of an instrument for steering the distal end. No cylinder coupled to a piston is described in Swain '153 or 730, or Yoon, for steering. Accordingly, Claim 68 is believed patentable over Swain '153 or 730, and Yoon, either alone, or in combination.

Claims 69-71 have been added to the application. Claim 69 describes a folding piston coupled to the distal end of an instrument for steering the distal end. Claim 70 describes the folding piston as being a tube of plastic material having closed ends and radial zones of reduced diameter axially spaced along the tube to provide longitudinal expansion or contraction along the zones in response to changes in volume of a medium in the tube. Claim 71 describes this medium as representing a fluid. No folding piston is described in Swain '153 or 730, or Yoon, for steering. Thus, Claims 69-71 are believed patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claim 72 has also been added to the application. Claim 72 describes a method for endoscopically passing an instrument into a patient by providing an endoscope having a flexible shaft and an accessory tube coupled externally to the shaft which flexes in accordance with flexing of the shaft, locating an endoscope with the coupled accessory tube in the body of a patient, and inserting one or more instruments through the accessory tube into the body of the patient. For reasons argued with respect to Claim 1, Claim 72 is believed patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claim 73 has further been added to the application. Claim 73 describes a system of endoscopic suturing having means for attaching an external tube along a flexible shaft of an endoscope to flex with flexing of the shaft, a suturing instrument locatable through the external tube attached to the endoscope to locate at least one loop of suture through tissue in a body of a patient, and a suture securing instrument having at least a partially flexible shaft which is locatable through the external tube attached to the endoscope to retain in a sleeve member the loop of suture and then cut the suture extending from the sleeve member to secure the suture in the tissue. No means for attaching a flexible tube is provided along the shaft of any endoscope in Swain '153 or '730, or Yoon. For reasons argued with respect to Claims 21-23, no suture securing instrument is provided in Swain '153 or 730, or Yoon, which retains in a sleeve member the loop of suture and then cuts the suture extending from such sleeve member to secure the

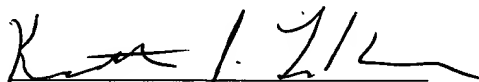
suture in the tissue. Therefore, Claim 73 is believed patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

Claim 74 has been added to the application. Claim 74 describes a system of endoscopic suturing having an endoscope locatable in the body of a patient having a flexible shaft with a steerable distal end, a flexible guide tube having first and second ends locatable outside the shaft, and have the first end attached to the distal end of the shaft to be steered with steering of the distal end of the endoscope, and at least one tissue suturing instrument having a shaft which is sufficiently flexible to be insertable through the flexible guide tube when the flexible guide tube is located in a body of a patient. No flexible guide tube is provided outside the shaft of any endoscope in Swain '153 or '730, or Yoon for reasons argued earlier. Thus, Claim 74 is believed patentable over Swain '153, Swain '730, and Yoon, either alone, or in combination.

It is believed the application is in a condition for Allowance. A petition for a three month extension of time is enclosed with the \$1,071.00 for the petition fee and additional filing fee charged to a deposit account.

Respectfully submitted,

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Enclosures: Combined Amendment and Petition for Extension of Time Transmittal Letter;  
Certificate of Express Mail, Express Mail No. EV 325176369 US; and  
Listing of Claims.

LISTING OF CLAIMS

1. (currently amended) A system for endoscopic suturing using an endoscope having a flexible shaft with a distal end comprising:

~~an endoscope locatable in the body of a patient having a flexible shaft;~~

a flexible tube having first and second ends, said flexible tube being attachable at one or more locations along the outside of said shaft of said endoscope to enable said tube and coupled to said endoscope to be movable flex with flexing of said shaft of said endoscope; and

a tip attachable coupled to said distal end of said shaft of said endoscope having an opening through which said second end of said flexible tube is received; and, wherein said flexible tube operates as a conduit for passage of one or more instruments.

~~at least one tissue suturing instrument having a shaft locatable through said first and second ends of said tube.~~

2. (currently amended) The system according to Claim 1 further comprising:

a plurality of tube guides, means for attaching each of said plurality of tube guides being attachable at a different one of said locations along the outside of said shaft of said endoscope and has an opening through which said flexible tube extends, and said flexible tube is slidable through said opening of the tube guide in response to flexing of said shaft of said endoscope said tube at a plurality of locations along said shaft of said endoscope to enable said tube to be substantially coaxial with said shaft of said endoscope while movable through said attaching means.

3. (currently amended) The system according to Claim 1 further comprising:

a cannula attached to said first end of said ~~accessory~~ flexible tube in which ~~said shaft of said suturing instrument~~ each of said instruments passes through said cannula to into said flexible tube.

4. (currently amended) The system according to Claim 1 wherein at least one of said instruments represents a said shaft of said suturing instrument having a shaft sufficiently is at least partially flexible to enable passage through said tube.

5. (currently amended) The system according to Claim 1 4 wherein said tissue suturing instrument further comprises means for engaging tissue having a sew tip with a gap, said sew tip being coupled to said shaft of said tissue suturing instrument, and a sleeve over said sew tip having one end capped and an opening to at least said gap, and said system further comprising means for providing suction is a channel along said shaft to said gap of said sew tip to enable tissue to be pulled into said gap.

6. (original) The system according to Claim 5 wherein said tissue suturing instrument has at least one needle in said sew tip, and means for driving said needle forward through said suctioned tissue into a ferrule having one end of suture, and retracting said needle through said suction tissue with said ferrule.

7. (currently amended) The system according to Claim 1 4 wherein said suturing instrument further comprises a tissue engaging end coupled to said shaft of said suturing instrument, and said shaft of said suturing instrument has a channel for applying suction to said tissue engaging end of said tissue suturing instrument, and means for connecting to said channel through said shaft of said suturing instrument for applying vacuum establishing said suction.

8. (currently amended) The system according to Claim 1 4 wherein said suturing instrument further comprises a tissue engaging end coupled to said shaft of said suturing instrument and a housing coupled to said shaft of said instrument, in which said shaft of said suturing instrument has a first section and a second section, and said first section is rigid and extends from said housing, and said second section is flexible and extends from the first section to the tissue engaging end of said suturing instrument.

9. (currently amended) The system according to Claim 8 wherein said first section of said shaft of said suturing instrument has a rigid tube and a first guide member in said tube having a plurality of tracks for at least one needle and suture, and said second section of said shaft has a second guide member having a plurality of tracks for at least one needle and suture, and said shaft has a coupler member for coupling said first and second guide members to each other.

10. (currently amended) The system according to Claim 9 wherein a wire is attached to said coupler member through said second guide member and attached into said tissue engaging end.

11. (currently amended) The system according to Claim 8 wherein said suturing instrument further comprising comprises means for translating rotation of one of said housing and said first section ~~of said shaft~~ to said second section of said shaft and said tissue engaging end of said suturing instrument.

12. (currently amended) The system according to Claim 8 wherein said suturing instrument ~~has~~ further comprises at least one needle which extends through said shaft of the suturing instrument to said tissue engaging end.

13. (currently amended) The system according to Claim 8 wherein said suturing instrument ~~has~~ further comprises one or more needles which extends through said shaft of the suturing instrument to said tissue engaging end, in which each of said needles comprises first and second members and a spring which couples said first and second members, and said second member has a tip positionable in said tissue engaging end.

14. (currently amended) The system according to Claim 13 wherein said second section of said shaft of said suturing instrument has a tube having holes extending through said tube of said second section for at least said needles.

15. (currently amended) The system according to Claim 13 wherein said second section of said shaft of said suturing instrument has a flexible tube for each of said needles, and each of said needles passes through said flexible tube of said second section to said tissue engaging end.

16. (currently amended) The system according to Claim 15 wherein said flexible tube of said second section of said shaft of said suturing instrument comprises a spring having two ends and having an outer sheath attached to said two ends to restrict elongation of the spring ~~of said flexible tube~~ while enabling flexure of the flexible tube of said second section.



17. (currently amended) The system according to Claim 13 wherein said ~~needle extends~~ needles extend through said shaft of the suturing instrument and said spring of each of said ~~needle~~ needles is located in said ~~flexible~~ second section to assist in flexibility of said ~~needle~~ needles.

18. (currently amended) The system according to Claim 13 wherein each of said needles further comprises a cable or wire which couples said spring between said first and second members.

19. (currently amended) The system according to Claim 1 wherein said system further comprises an endoscope is representing a gastroscope.

20. (currently amended) The system according to Claim 1 wherein said ~~suturing instrument~~ instruments are capable of operating ~~operates~~ independently of said endoscope.

21. (currently amended) The system according to Claim 1 wherein at least one of said instruments represents further comprising a suture securing instrument having a shaft locatable through said first and second ends of said accessory tube.

22. (currently amended) The system according to Claim 21 wherein ~~said shaft of~~ said suture securing instrument comprises a shaft which is at least partially flexible to enable passage through said ~~accessory~~ tube.

23. (original) The system according to Claim 21 wherein said suture securing instrument further comprises means for retaining in a sleeve member the two free ends of a loop of suture extending through tissue, and means for cutting the two free ends of the loop of suture near said sleeve member.

24. (currently amended) The system according to Claim ~~1~~ 21 wherein said suture securing instrument ~~operates independently of said~~ is not part of an endoscope.

25. (currently amended) The system according to Claim 1 wherein said shaft at least one of said instruments has a shaft having a distal end, and said system further comprises an

endoscope ~~provides~~ having means for viewing the distal end of said one of said instruments ~~suturing instrument~~ when said distal tissue engaging end is located through said first and second ends of said tube.

26. (currently amended) The system according to Claim 1 ~~4~~ wherein said shaft of said suturing instrument has a distal tissue engaging end, and has a channel for applying positive or negative air pressure to said end of said tissue suturing instrument, and means for connecting to said channel through said shaft for applying said positive or negative air pressure.

27. (currently amended) The system according to Claim 1 ~~4~~ wherein said suturing instrument further comprises a distal tissue engaging end coupled to said shaft of said suturing instrument, in which said shaft of said suturing instrument has a channel to said tissue engaging end and an opening to said channel, and said flexible tube has a port capable of enabling suction to be provided to said tissue engaging end through said opening and channel of said shaft, in which said opening of said tip has a seal for engaging with said tissue engaging end of said suturing instrument to enable said suction to be provided through said opening of said shaft.

28. (currently amended) The system according to Claim 1 further comprising an endoscope having a ~~wherein said shaft attached to said flexible tube of said endoscope has a distal end and said tip is coupled to said shaft at said distal end.~~

29. (currently amended) The system according to Claim 1 further comprising means for locking ~~at the tip of said tube~~ the position of at least one of said instruments ~~the suturing instrument~~ with respect to said flexible tube at the tip of said flexible tube.

30. (currently amended) The system according to Claim 1 ~~29~~ wherein at least one of said instruments represents has a shaft sufficiently flexible to enable passage through said tube, and said shaft of said one of said instruments has a distal ~~said suturing instrument further comprises a tissue engaging end coupled to the shaft of said suturing instrument and said tissue engaging end being~~ having a substantially cylindrical ~~with an~~ outer surface with having one or more protrusion members along said outer surface of said distal end, and said opening of said tip having one or more slots into which said protrusion members are ~~received~~ receivable to lock the

position of said one of said instruments ~~the suturing instrument~~ with respect to said flexible tube at said tip.

31. (currently amended) The system according to Claim 1 ~~4~~ wherein said suturing instrument further comprises a tissue engaging end coupled to the shaft of said suturing instrument, and means for steering said tissue engaging end.

32. (original) The system according to Claim 31 wherein said steering means is one of hydraulically and mechanically actuated.

33. (currently amended) A method for suturing tissue comprising the ~~step~~ steps of:  
providing an endoscope having a flexible shaft and an accessory tube coupled externally to said shaft which flexes in accordance with flexing of said shaft;

locating an endoscope with said ~~coupled to an accessory tube in the body through the gastrointestinal tract~~ of a patient; and

inserting a suturing instrument through said accessory tube into the body of the patient to place two ends of a loop of suture through tissue of the gastrointestinal tract;

removing said suturing instrument to leave a loop of suture in the tissue having two free and extending from the accessory tube;

inserting a suture securing instrument having a distal end with a sleeve member through which the free ends of the suture loop are drawn to the suture in the tissue to crimp the sleeve member and cut the free ends of the suture; and

removing said suture securing instrument from said accessory tube.

34. (currently amended) The method according to Claim 33 wherein said inserting step further comprises the ~~step~~ steps of:

providing a shaft for said suturing instrument and a distal tissue engaging end coupled to said shaft of said suturing instrument having a sew tip with a gap, and a sleeve over said sew tip having one end capped and an opening to at least said gap; and

applying suction to a channel along said shaft to said gap of said sew tip to enable tissue to be pulled into said gap when each end of said loop of suture is place in tissue.

35. (currently amended) An attachment for a flexible endoscope having a shaft extending to ~~said a~~ distal end comprising:

a flexible tube capable of being coupled externally to said endoscope to be flexible with flexing of said shaft of said endoscope; and

said tube having a distal end attached to said shaft of said endoscope

~~a tip coupled to said shaft of said endoscope having an opening through which said tube is received.~~

36. (currently amended) The attachment according to Claim 35 wherein said proximal end of said tube has a sealable opening which opens to allow an instrument to pass into said tube and closes when the instrument is removed from the tube ~~shaft of said endoscope has a distal end and said tip is coupled to said shaft at said distal end.~~

37. (currently amended) The attachment according to Claim 35 further comprising:  
a plurality of guides each attached at a location along said shaft of said endoscope and having an opening through which said tube extends in which said tube is capable of ~~moving~~ sliding through said opening in response to flexing of said shaft of said endoscope.

38. (currently amended) The attachment according to Claim ~~36~~ 35 ~~further comprising:~~  
wherein said sealable opening is provided by a cannula attached to said tube and having a sealable passage in communication with said tube.

39. (currently amended) The attachment according to Claim 35 wherein said tube represents a conduit enabling ~~enables~~ access of an instrument independent of said endoscope near said distal end of the shaft of the endoscope.

40. (currently amended) A suturing instrument comprising:  
a housing;  
a shaft extending from said housing;  
a tissue engaging end coupled to said shaft at the distal end of the instrument;  
one or more needles which extend through said housing through said shaft to said tissue engaging end;

a suture channel extending through said housing and said shaft to said tissue engaging end;

said tissue engaging end having a sew tip with an opening through which said needles are extendable to each capture one end of suture extending through said suture channel to said sew tip; and

said shaft ~~representing an assembly~~ having a first section and a second section, said first section being rigid and extends from said housing, and said second section being flexible and extends from the first section to the tissue engaging end of said suturing instrument.

41. (currently amended) The suturing instrument of Claim 40 wherein said opening of said sew tip represents a first opening and said suture channel having first and second end in which said first end is adjacent said sew tip, and said suturing instrument further comprises:

a sleeve over said sew tip having one end capped and an second opening in communication with said first opening of said sew tip;

means for selectably providing suction to said suture channel along said shaft to said first opening of said sew tip to enable tissue to be pulled into said first opening through said second opening of said sleeve when said needle extends through said opening of said sew tip in which said capped sleeve enables suction to be communicated to said distal end of the instrument; and

means for selectably closing said second end of said suture channel to enable suction to be provided at said sew tip by said suction providing means.

42. (original) The suturing instrument of Claim 40 wherein said needle comprises first and second members and a spring which couples said first and second members, and said second member has a tip positionable in said sew tip.

43. (currently amended) A suture securing instrument comprising:

~~a housing;~~

a shaft ~~extending from said housing~~ which is at least partially flexible;

a distal tissue end coupled to said shaft;

~~said shaft representing an assembly having a first section and a second section, said first section being rigid and extends from said housing, and said second section being flexible and extends from the first section to the distal end of said instrument;~~

means for retaining in a sleeve member at said distal end two free ends of a loop of suture extending through tissue; and

means for cutting the two free ends of the loop of suture near said sleeve member.

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44. (currently amended) A system for endoscopic suturing in the body of a patient comprising:

an endoscope having a shaft and an internal channel along said shaft locatable in the body of a patient;

a suturing instrument having at least a partially flexible shaft which is locatable through said internal channel of said endoscope to locate at least one loop of suture in the body of a patient; and for enabling suturing of tissue of the patient

a suture securing instrument having at least a partially flexible shaft which is locatable through said internal channel of said endoscope to retain in a sleeve member the loop of suture and then cut the suture extending from said sleeve member to secure said suture in the body of the patient.

45. (new) The system according to Claim 1 wherein said flexible tube is attachable to and detachable from different types of endoscopes.

46. (new) The system according to Claim 1 wherein said system further comprises an endoscope having a shaft with a channel for passage of tools and said flexible tube is of a diameter larger than said channel.

47. (new) The system according to Claim 1 wherein each of said instruments is sufficiently flexible to be locatable through said first and second ends of said tube when having one or more flexures in accordance with flexing of said shaft of said endoscope.

48. (new) The system according to Claim 22 wherein said an endoscope has an internal channel along said shaft, and said suture securing instrument is locatable through said internal channel of said endoscope.

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said tissue engaging end having an opening to a cavity through which said needles are extendable to each capture one end of the suture; and

means for applying suction along said shaft to said cavity of said tissue engaging end to enable tissue to be pulled into said opening when said needles are extended, wherein said shaft is not part of an endoscope.

55. (new) The suturing instrument according to Claim 54 said suction applying means further comprises a capped sleeve containing said tissue engaging end and having an opening in communication with said opening of said tissue engaging end.

56. (new) The suturing instrument according to Claim 54 further comprising a foldable piston coupled to said tissue engaging end, and means for controlling the volume of a medium in said foldable piston to steer said tissue engaging end.

57. (new) The suturing instrument according to Claim 54 further comprising a cylinder having a movable piston coupled to said tissue engaging end, and means for controlling the volume of a liquid in said cylinder to move said piston and steer said tissue engaging end.

58. (new) The suturing instrument according to Claim 54 further comprising a wire extending along said shaft and coupled to said tissue engaging end, and means for controlling the length of said wire along said shaft to steer said tissue engaging end.

59. (new) The suturing instrument according to Claim 54 wherein said suturing instrument is locatable through an internal channel of an endoscope.

60. (new) The suturing instrument according to Claim 54 wherein said suturing instrument is locatable through an accessory tube located outside along a shaft of an endoscope.

61. (new) The suturing instrument according to Claim 54 wherein said shaft of said suturing instrument has a first section and a second section, and said second section is substantially more flexible than said first section and extends from the first section to said tissue engaging end, and said suturing instrument further comprises means for translating rotation from

49. (new) The method according to Claim 33 wherein said locating step further comprising the step of locating the endoscope with said coupled accessory tube in the gastrointestinal tract of a patient.

50. (new) The method according to Claim 33 further comprising the steps of:  
removing said suturing instrument to leave a loop of suture in the tissue having two free and extending from the accessory tube;  
inserting a suture securing instrument having a distal end with a sleeve member through which the free ends of the suture loop are drawn to the suture in the tissue to crimp the sleeve member and cut the free ends of the suture; and  
removing said suture securing instrument from said accessory tube.

51. (new) The attachment according to Claim 35 further comprising:  
one or more first members through which said tube is slidable and said first members are attachable at locations along said shaft of said endoscope; and  
a second member attached to said distal end of said tube in which said second member is attachable to the distal end of the shaft of the endoscope, in which said tube operates as a conduit for passage or one or more instruments along outside said shaft of said endoscope.

52. (new) The suture securing instrument according to Claim 43 further comprising a housing, wherein said shaft extends from said housing to said distal end of said instrument.

53. (new) The suture securing instrument according to Claim 52 wherein said shaft has a first section and a second section, said first section being rigid and extends from said housing, and said second section being flexible and extends from the first section to the distal end of said instrument.

54. (new) A suturing instrument comprising:  
a shaft;  
a tissue engaging end coupled to said shaft at the distal end of the instrument;  
one or more needles which extend through said shaft to said tissue engaging end;  
means for carrying suture along said shaft to said tissue engaging end;



said first section of said shaft to both said second section of said shaft and said tissue engaging end.

62. (new) The suturing instrument according to Claim 54 wherein each of said needles comprises first and second members and a spring which couples said first and second members to aid in flexibility of said needles.

63. (new) The suturing instrument according to Claim 60 wherein each of said needles further comprises a cable or wire which couples said spring between said first and second members.

64. (new) A instrument for suturing tissue comprising:  
a housing;  
a shaft which is at least partially flexible;  
a tissue engaging end coupled to said second section of said shaft; and  
one or more needles which extend through said first and second sections of said shaft capable of engaging tissue at said tissue engaging end, each of said needles comprises first and second members and a spring which couples said first and second members to aid in flexibility of said needles.

65. (new) The <sup>112</sup>system according to Claim 64 wherein each of said needles further comprises a cable or wire which couples said spring between said first and second members.

66. (new) A instrument for suturing tissue comprising:  
a housing;  
a shaft extending from said housing having a first section and a second section;  
a tissue engaging end coupled to said second section of said shaft;  
one or more needles which extend through said first and second sections of said shaft to said tissue engaging end;  
a suture channel extending through said first and second sections of said shaft to said tissue engaging end;  
said first section has an outer tube and a first guide member extending in said tube having a plurality of tracks for said needles and suture;

said second section of said shaft has a second guide member having a plurality of tracks for said needles and suture; and

said shaft has an outer layer extending over at least said second guide member to said tissue engaging end, and a coupler member coupling said first guide member to said second guide member to enable rotation to be translated from said first section to said tissue engaging end through said second section.

67. (new) The instrument according to Claim 66 further comprising a wire attached to said coupler member and extending through an opening of said second guide member and attached into tissue engaging end.

68. (new) An instrument comprising:

a housing, a distal end, and a shaft extending from said housing to said distal end;

a chamber at said housing having a fluid and a piston in said chamber movable to change the volume of the fluid in said chamber, an opening to said chamber, and a tube coupled to said opening extending along said shaft to said distal end; and

a cylinder along said shaft having a piston coupled to said distal end movable responsive to changes in said volume of fluid in said chamber communicated through said tube to said cylinder to steer said distal end.

69. (new) An instrument comprising:

a housing, a distal end, and a shaft extending from said housing to said distal end;

a chamber at said housing having a medium and a piston in said chamber movable to change the volume of said medium in said chamber, an opening in said chamber, and a tube coupled to said opening extending along said shaft to said distal end; and

a folding piston coupled to said distal end expandable and retractable responsive to changes in said volume of said medium in said chamber communicated through said tube to said cylinder to steer said distal end.

70. (new) The instrument according to Claim 69 wherein said folding piston comprises a tube of plastic material having closed ends and radial zones of reduced diameter axially spaced along said tube to provide longitudinal expansion or contraction along said zones in response to changes in volume of said medium in said tube.

71. (new) The instrument according to Claim 69 wherein said medium represents a fluid.

72. (new) A method for endoscopically passing an instrument into a patient comprising the steps of:

providing an endoscope having a flexible shaft and an accessory tube coupled externally to said shaft which flexes in accordance with flexing of said shaft;

locating an endoscope with said coupled accessory tube in the body of a patient; and

inserting one or more instruments through said accessory tube into the body of the patient.

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73. (new) A system of endoscopic suturing comprising:

means for attaching an external tube along a flexible shaft of an endoscope to flex with flexing of said shaft;

a suturing instrument locatable through said external tube attached to said endoscope to locate at least one loop of suture through tissue in a body of a patient; and

a suture securing instrument having at least a partially flexible shaft which is locatable through said external tube attached to said endoscope to retain in a sleeve member the loop of suture and then cut the suture extending from said sleeve member to secure said suture in the tissue.

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74. (new) A system of endoscopic suturing comprising:

an endoscope locatable in the body of a patient having a flexible shaft with a steerable distal end;

a flexible guide tube having first and second ends locatable outside said shaft, and have the first end attached to the distal end of said shaft to be steered with steering of said distal end of said endoscope; and

at least one tissue suturing instrument having a shaft which is sufficiently flexible to be insertable through the flexible guide tube when the flexible guide tube is located in a body of a patient.

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